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B. Webb
11/19/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF
LESSER *et al.*
Appln. No.: 09/691,051
Filed: October 19, 2000

Confirmation No.: 5363
Group Art Unit: 3762
Examiner: OROPEZA, FRANCES P.

Title: TECHNIQUES USING HEAT FLOW MANAGEMENT STIMULATION AND SIGNAL ANALYSIS TO TREAT MEDICAL DISORDERS

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JOINT DECLARATION OF RONALD P. LESSER, M.D., AND W. ROBERT S. WEBBER, Ph.D., UNDER 37 C.F.R. § 1.132

We, RONALD P. LESSER, M.D. and W. ROBERT S. WEBBER, Ph.D. declare as follows:

1. We are co-inventors of the subject matter claimed in the above-identified U.S. patent application, which is currently being examined by the United States Patent and Trademark Office.

2. Dr. Lesser is presently a Professor of Neurology and Neurosurgery at the Johns Hopkins University School of Medicine in Baltimore, Maryland. Dr. Lesser's full *curriculum vitae* is attached to this Declaration as Exhibit A.

3. Dr. Webber is presently a Research Associate in the Department of Neurology at the Johns Hopkins University School of Medicine in Baltimore, MD. Dr. Webber's full *curriculum vitae* is attached to this Declaration as Exhibit B.

4. We have both reviewed and are familiar with the contents of the official action dated August 11, 2003. We have also reviewed and are familiar with the references cited by the patent examiner in that official action. We note that most of the references cited by the patent examiner in the August 11 official action were also cited in an official action dated October 1, 2002. We have reviewed and are familiar with the October 1, 2002 official action as well.

5. We understand that some of the claims in our patent application are presently rejected as allegedly unpatentable over U.S. Patent No. 5,995,868, issued to Dorfmeister, *et al.* (hereinafter the "'868 patent"), both alone and in various combinations with other references.

6. Each of our presently pending independent claims, *i.e.*, claims 35, 51, and 57, recites "performing a wavelet cross-correlation analysis." We do not believe that the '868 patent discloses wavelet cross-correlation analysis or would suggest wavelet cross-correlation analysis to a skilled practitioner, either alone or in combination with other references. Therefore, we directed our attorneys to point out that distinction, among others, in response to the October 2, 2002 official action.

7. We understand that the patent examiner has maintained the rejection of the claims. We note paragraph 4 of the official action, in which the patent examiner states "signal processing [disclosed in the '868 patent] includes adaptive analysis of waveform characteristics such as wavelet transform analysis[.] Coherence analysis, also known as cross correlation analysis, is disclosed for use with wavelet transform." We disagree with the patent examiner's assertion that coherence analysis is equivalent to or "also known as" correlation analysis. We also disagree with the patent examiner's assertion that coherence analysis is taught for use with the wavelet transform. For those reasons, we offer the following explanation and comparison of coherence analysis and cross-correlation analysis.

8. Coherence analysis measures a relationship between two signals of equal length in the frequency domain. In order to perform a coherence analysis, the signals to be analyzed must first be transformed into the frequency domain. That transformation step is commonly performed using the Fourier transform, usually by means of the Fast Fourier Transform (FFT).

9. The coherence of two frequency-domain input signals is determined by breaking the two signals into sections. For each pair of sections, a FFT is calculated. The cross-spectrum for each pair of sections is then calculated by multiplying them together frequency point by frequency point. The cross-spectra are then summed together and normalized by the power spectra of each of the original input signals. The output of a coherence analysis is thus a function of frequency with a value between zero and one. There are many fewer points in the coherence function than in the original signals.

10. Cross-correlation, on the other hand, works directly with signals in the time domain. It measures the strength of the time domain signal that is common to two input signals being measured. The two input signals may be of different lengths. Cross-correlation also indicates the time delay of the common signal component from one input signal to the other. The cross-correlation output is a function of time in arbitrary units. The cross-correlation is calculated by multiplying the time points of one signal by the time points of the other signal and summing the results to produce one point in the output cross-correlation. This process is repeated after shifting one time signal one sample point with respect to the other to produce the next point in the cross-correlation output. If the one signal is N samples long and the other is M samples long, the result is N + M -1 samples long. Thus, the output cross-correlation function has more points than the input signals.

11. In coherence analysis, the coherence function is an average estimate of a number of smaller sections of the original signals. It is not possible to compute the coherence from one section of each signal. If one were to do that, the result would be the value 1.0 for all frequencies. Coherence gives an estimate of the variability of the phase difference between two signals as a function of frequency. The coherence function has established statistical properties that depend on the number of sections taken from the original signal. By

contrast, the cross-correlation function can be and often is calculated for one time span of each time signal. It is not an estimate or average and does not have established statistical properties.

12. We also note that it is not possible to calculate the cross-correlation from the coherence, which indicates that each function contains some unique information about the relationship between the two input signals.

13. After reviewing the August 11 official action and the cited references, we suspect that the patent examiner may have taken the position that coherence and cross-correlation are equivalent because of some of the disclosure in U.S. Patent No. 6,594,524, issued to Esteller, *et al.* (hereinafter the "'524 patent"). In column 27, at line 55, the '524 patent describes coherence as "the signal processing name for the cross-correlation between two frequency spectra." We disagree with that definition, and we believe that no practitioner of skill in the art would accept it. It appears to us that that definition is probably an error or mischaracterization on the part of the patent drafter.

14. Additionally, with respect to the '524 patent, we note that the formula given in column 28, at line 3. does not contain the traditional cross-multiplication and shift used in cross-correlation calculations. In fact, it contains elements not found in the traditional coherence calculation, *i.e.*, normalization by a maximum of spectra and the product sign, which seems to conflict with the description of the formula that follows it.

15. In summary, coherence is not the same as cross-correlation.

16. We also declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of

United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application, or any patent issuing thereof.

Respectfully submitted,

Ronald P Lesser MD Date: Nov 11, 2003

Ronald P. Lesser, M.D.

W.R.S. Webber Date: 11 NOV 2003

W. Robert S. Webber, Ph.D.